

U.S. Application No.: 09/438,759

AMENDMENT D AND REQUEST FOR TELEPHONE INTERVIEW

Attorney Docket: 2368/098

REMARKS

Review and reconsideration of the Office Action of August 13, 2003, is respectfully requested in view of the above amendments and the following remarks.

Claim 16 has been canceled.

Claims 12, 19, 23, and 26 have been amended by adding the limitation "inlet funnel shaped opening". Support for claims amendment can be found in canceled claim 16, Figures 2-3, element 32, and page 6, lines 29-30 of the specification.

Care has been taken to ensure that no new matter is added to the claims.

Applicants respectfully request that the Examiner re-considered the finality of the outstanding Office Action. Reasons are as follows:

- 1) the Examiner cited new prior art that was not cited before;
- 2) a second or any subsequent action on the merits in any application or patent involved in examination proceedings should not be made final if it includes a rejection, on prior art not of record, of any claim amended to include limitations which should reasonably have been expected to be claimed.

In the instant case, Claims 12 and 19 were amended by including the limitation "rigid hollow" and deleting the limitation cannula. The added limitation should reasonably have been expected to be claimed because the tube, according to the

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present invention, must be rigid in order to pierce the skin. Furthermore, a person skilled in the art will understand that being rigid is an intrinsic property of a cannula used to pierce the skin.

Thus, the finality of the Office Action is improper.

In addition, Applicants reviewed the '742 (main reference) reference and note that compared with independent Claims 12, 19, 23, and 26, the reference fails to teach: 1) a unipolar cannula; 2) an inlet funnel shaped opening; and 3) a sharp tip.

Regarding point 1

Applicants note that the present invention is directed to a unipolar cannula, i.e. the cannula has only one electrode. A unipolar cannula (one electrode) is used for electro-stimulation of the nerve. The electro-stimulation needs only minimal voltage and no electrical power.

The '742 reference requires an electrical conductor connectable to a conventional source of high frequency current.

Regarding point 2

Applicant notes that the Examiner indicated that Figure 7B of the '742 reference shows an inlet funnel. The Examiner's indication is incorrect. Figure 7B shows the distal end of the cannula and not the proximal end.

The '742 reference does not show a cannula for introducing a catheter. The proximal end of the cannula 22, projects freely into the hollow cavity of the handle as shown in Figure 1C. If a catheter would be introduced into the hollow cavity 26 of the

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handle 14, the catheter would be caught by the proximal end of the cannula and would not be guided into the cannula.

It is important for the cannula of the present invention that a catheter be introduced into the proximal end of the cannula through the body part. Therefore the body part has an inlet opening axially aligned with the cannula tube and forming an inlet funnel 32.

Regarding point 3

The Examiner is of the opinion that the reference discloses a sharp tip. Applicants completely disagree with the Examiner's opinion.

The reference is directed to a suction electro-coagulator device having an anti-clogging tip. The device is used for helping during procedures such as tonsillectomy, adenoidectomy, or sinuscopy. (Column 7, lines 1-2).

A person skilled in the art will not expect that an instrument that is used to suction viscous fluid such as sinus and adenoids will have a sharp tip. In addition, if such devices include a sharp tip, the patient can be cut by accident during the suction of the fluid.

Thus, the tip of the reference is not, and cannot be, sharp. Furthermore, there is no technological motivation to include a sharp tip in the device of the '724 reference.

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Applicants reviewed the '341 reference and note that compared with independent Claims 12, 19, 23, and 26, the reference fails to teach: 1) conductive unipolar cannula for anesthesia; 2) an electrically conductive rigid hollow tube; 3) a sharp tip; 4) a body part provided at the proximal end of the cannula tube; 5) a connector electrically connected to the cannula tube; 6) an outer covering extending from the body part out to the sharp tip; and 7) an inlet funnel shaped opening.

The first thing that Applicants note is that the reference is not directed to a cannula for anesthesia. Thus, Applicants do not consider this reference to be in the same field of the invention.

Combining the references

Applicants note that the '341 reference does not overcome the deficiencies of the '742 reference. Thus, neither the references taken alone or in combination teach the subject matter claimed in the present invention.

In addition, if the references are combined, it "would require a substantial reconstruction and redesign of the elements shown in the '742 reference, as well as a change in the basic principles under which that reference's construction was designed to operate." Thus, a person skilled in the art will not consider combining the references.

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Office Action

Turning now to the Office Action in greater detail, the paragraphing of the Examiner is adopted.

Paragraph 1 (Anticipation)

The Examiner rejects Claims 12, 15-17, 19-22, and 26 under 35 U.S.C. 103(a) as anticipated by Wojciechowicz (5,730,742).

The position of the Examiner can be found on pages 2-3 of the Office Action.

Applicants respectfully traverse.

For a reference to anticipate, it must disclose all the elements of the claim.

Applicants reviewed the '742 reference and note that compared with independent Claims 12, 19, 23, and 26, the reference fails to teach: 1) a unipolar cannula; 2) an inlet funnel shaped opening; and 3) a sharp tip.

Regarding point 1

Applicants note that the present invention is directed to a unipolar cannula, i.e. the cannula has only one electrode. A unipolar cannula (one electrode) is used for electro-stimulation of the nerve. The electro-stimulation needs only minimal voltage and no electrical power.

The '742 reference requires an electrical conductor connectable to a conventional source of high frequency current.

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indication is incorrect. Figure 7B shows the distal end of the cannula and not the proximal end.

The '742 reference does not show a cannula for introducing a catheter. The proximal end of the cannula 22, projects freely into the hollow cavity of the handle as shown in Figure 1C. If a catheter would be introduced into the hollow cavity 26 of the handle 14, the catheter would be caught by the proximal end of the cannula and would not be guided into the cannula.

It is important for the cannula of the present invention that a catheter be introduced into the proximal end of the cannula through the body part. Therefore the body part has an inlet opening axially aligned with the cannula tube and forming an inlet funnel 32.

Regarding point 3

The Examiner is of the opinion that the reference discloses a sharp tip. Applicants completely disagree with the Examiner's opinion.

The reference is directed to a suction electro-coagulator device having an anti-clogging tip. The device is used for helping during procedures such as tonsillectomy, adenoidectomy, or sinuscopy. (Column 7, lines 1-2).

A person skilled in the art will not expect that an instrument that is used to suction viscous fluid such as sinus and adenoids will have a sharp tip. In addition, if such devices include a sharp tip, the patient can be cut by accident during the suction of the fluid.

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In addition, Applicants note that in column 7, lines 3-8 state that:

"According to embodiment 80, it is desired to use a flared or bell-shaped tip 72, such as illustrated by embodiment 70 of FIG. 5, but, because of surgeon's preference, to limit the outside diameter of the bell OD._{sub.B} to approximately match the outside diameter OD._{sub.I} of the external insulation 18."

Thus, the tip of the cannula cannot be used for penetrating the nerve sheath. Furthermore, Applicants note that the penetration function is prevented by the inner insulating sleeve.

In addition, Applicants note that in column 8, lines 53-56 state that:

"It has been determined, however, that it is not desirable to make the tip too sharp. Accordingly, it is useful to sandblast the leading edge 106/206 a bit or, alternatively, leave a tongue of brass or stainless steel for the cutting edge."

According to the Western dictionary, the term "flared" means to expand or open outward in shape.

Finally, Applicants note that the main feature of the '724 reference is that the tip is anti-clogging. A person skilled in

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the art will know that in order to prevent the clogging of the tube, the tip should be of certain dimensions.

Thus, the tip of the reference is not, and cannot be, sharp. Furthermore, there is no technological motivation to include a sharp tip in the device of the '724 reference.

In addition, Applicants note that the reference is not directed to a cannula for anesthesia. Thus, Applicants do not consider this reference to be in the same field of the invention.

Claims 13-18 and 20-22 are novel in view of their dependency with novel Claims 12 or 19.

Accordingly, withdrawal of the rejection is respectfully requested.

Paragraph 2 (Obviousness)

The Examiner rejects Claims 13-14 under 35 U.S.C. as being obvious over Wojciechowicz (US 5,730,742) in view of Mower (US 4,765,341).

The position of the Examiner can be found on page 4 of the Office Action.

Applicants respectfully traverse for the same reasons as set forth in the previous paragraph and the following remarks:

The '742 reference was discussed above.

Applicants note that Claims 13 and 14 depend on Claim 12.

Applicants reviewed the '341 reference and note that compared with independent Claims 12, 19, 23, and 26, the reference fails to teach: 1) conductive unipolar cannula for anesthesia; 2) an electrically conductive rigid hollow tube; 3) a sharp tip; 4) a body part provided at the proximal end of the

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cannula tube; 5) a connector electrically connected to the cannula tube; 6) an outer covering extending from the body part out to the sharp tip; and 7) an inlet funnel shaped opening.

The first thing that Applicants note is that the reference is not directed to a cannula for anesthesia. Thus, Applicants do not consider this reference to be in the same field of the invention.

Combining the references

Applicants note that the '341 reference does not overcome the deficiencies of the '742 reference. Thus, neither the references taken alone or in combination teach the subject matter claimed in the present invention.

In addition, if the references are combined, it "would require a substantial reconstruction and redesign of the elements shown in the '742 reference, as well as a change in the basic principles under which that reference's construction was designed to operate." Thus, a person skilled in the art will not consider combining the references.

It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art."

The motivation to modify the prior art must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention. Evidence of such motivation may "flow from the prior

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art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved."

Using an Applicant's disclosure as a blueprint to reconstruct the claimed invention from isolated pieces of the prior art contravenes the statutory mandate of § 103 which requires judging obviousness at the point in time when the invention was made. See *Grain Processing Corp. v. American Maize-Products Co.*, 840 F.2d 902, 907, 5 U.S.P.Q.2d 1788, 1792 (Fed. Cir. 1988).

In addition, a proposed modification is inappropriate for an obviousness inquiry when the modification renders the prior art reference inoperable for its intended purpose. *In re Ratti*, 270 F.2d 810, 813, 123 U.S.P.Q. 349, 352 (C.C.P.A. 1959)

Accordingly, withdrawal of the rejection is respectfully requested.

Paragraph 3 (Obviousness)

The Examiner rejects Claims 18 and 23-25 under 35 U.S.C. as being obvious over Wojciechowicz (US 5,730,742).

The position of the Examiner can be found on pages 4-5 of the Office Action.

Applicants respectfully traverse for the same reasons as set forth in the previous paragraph and the following remarks:

The '742 reference was discussed above.

Claims 18 and 23-25 are novel in view of their dependency with novel Claims 12, 19, or 26.

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Accordingly, withdrawal of the rejection is respectfully requested.

Favorable consideration and early issuance of the Notice of Allowance is respectfully requested. The Examiner is respectfully requested to contact the undersigned so that a telephonic interview may be arranged.

Respectfully submitted,



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CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing AMENDMENT D AND REQUEST FOR TELEPHONE INTERVIEW for U.S. Application No. 09/438,759 filed November 11, 1999, is being facsimile transmitted to the Patent and Trademark Office, "AFTER FINAL" facsimile number (703) 305-7401 Attn: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on November 12, 2003.

Evelyn A. Defilló

Name of Person Signing Certification

Evelyn A. Defilló
Signature

Nov 12/03
Date

AUTHORIZATION TO CHARGE

The Commissioner is hereby authorized to charge any additional fees, which may be required at any time during the prosecution of this application without specific authorization, or credit any overpayment, to Deposit Account No. 16-0877.

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